# DSJ1&2-PR Exh 578

Message

**From**: Dughri, Darem [darem.dughri@walgreens.com]
**Sent**: 10/22/2012 8:49:21 PM
**To**: Polster, Tasha [tasha.polster@walgreens.com]
**Subject**: GFD PPt
**Attachments**: CSActionPlan_vF.pptx; CSActionPlan_store_6.11.12.pptx

Tasha,

I have attached two Powerpoints to this email. The first is what we presented to Market and District leaders (which is not posted). The second Powerpoint is what we provided to the store (which is available on StoreNet under the GFD policy located under Additional Resources on page 7). If you have any questions please let me know.

Thanks,
Darem

# Controlled Substance Action Plan

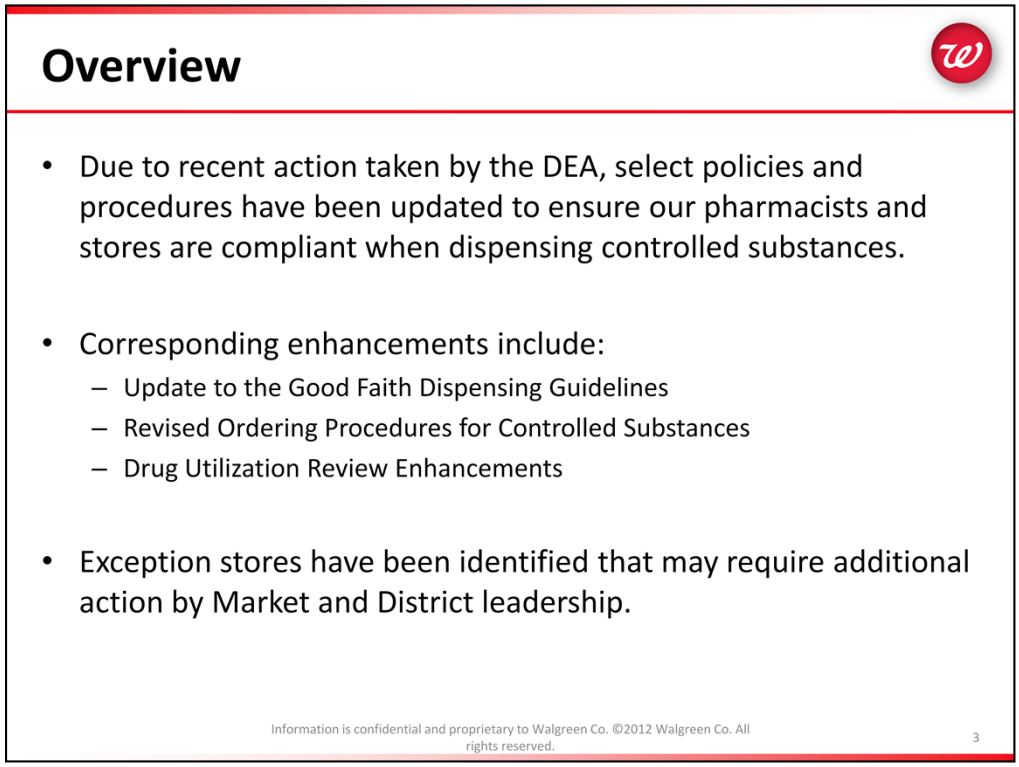
June 11th, 2012

# Agenda

- Overview
- Review updated policies & procedures
- Exception store visits
- Future Enhancements
- Call to action and next steps



2




Talking Points:

There has been recent action taken by the DEA with a few stores in Florida. Due to this action, we have taken a proactive approach to update our policies and procedures to include additional guidance and information for when our pharmacies dispense controlled substances. These enhancements include an update to the Good Faith Dispensing guidelines, revised ordering procedures for controlled substances and a DUR enhancement to alert our pharmacists on potential abuse.

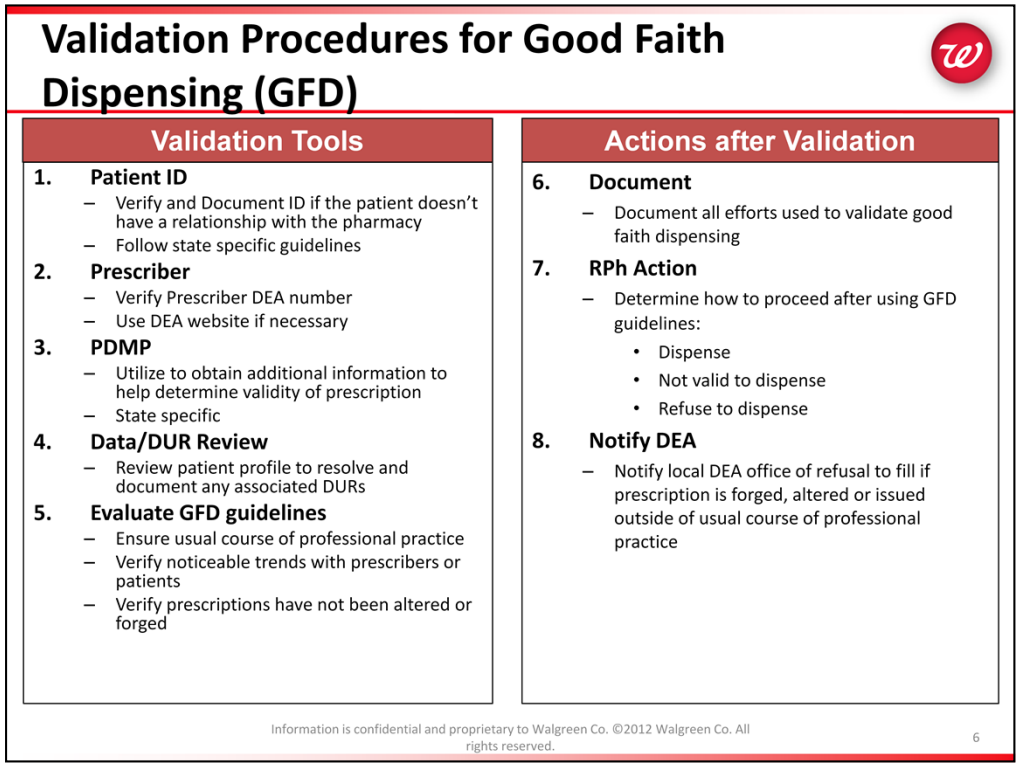
In addition to these enhancements, we are working proactively to identify stores that may be at risk today or in the future because of current dispensing trends. Market and District leadership, including Loss Prevention, will be required to work with these exception stores over the next few weeks to minimize risk for these locations.

- Overview
- Review updated policies & procedures
- Exception store visits
- Future Enhancements
- Call to action and next steps


As mentioned earlier, the Good Faith Dispensing policy has been updated to include additional guidance and resources to provide to our pharmacies when validating and dispensing Controlled Substances. Specifically, the following components have been updated: the elements of good faith dispensing, the prescription validation procedures and the roles and responsibilities of each pharmacy team member that handles the controlled substance prescription.

The updated policy can be found on StoreNet>Pharmacy Operations (RxOps) > Filling prescriptions > Controlled Substance Prescription & Good Faith Dispensing.

It's imperative that Market and District Leadership understands and communicates these guidelines to their team members.




Let's review the updated validation procedures contained in the Good Faith Dispensing Policy.

The first 5 steps describe how pharmacy team members are able to determine the validity of a prescription. The last 3 are actions that should be completed after the initial validation steps. Every situation will not be the same. In some circumstances, you will use all GFD tools, however in other situations you may only need to use a few. We expect our pharmacists to use their professional judgment when dispensing controls and document accordingly.

Key Points to Highlight:

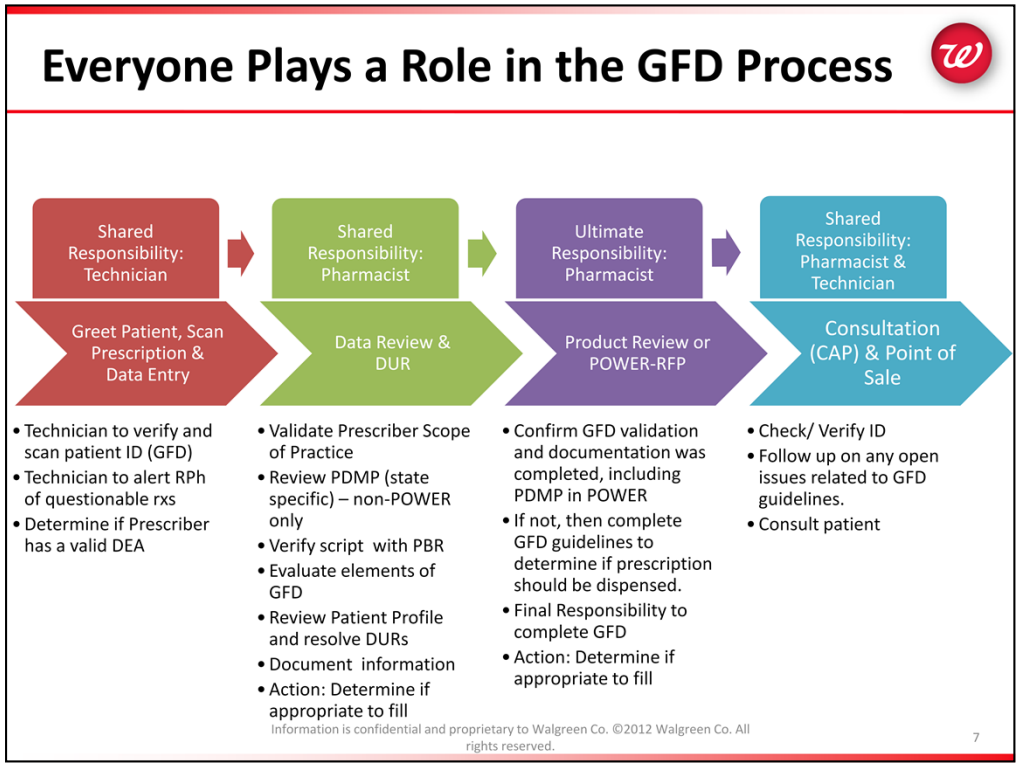
. Even if the prescriber verifies that the prescription is valid, it is the pharmacist's responsibility to confirm that the elements of good faith dispensing are satisfied prior to dispensing. It is not enough to only verify if a prescription is fraudulent.

In the policy, there are examples that should alert a pharmacist to questionable circumstances. Such as:

- Is the rx written outside the prescriber's scope of practice? For example, a pediatrician writing for an adult
- Does the prescriber frequently write for unusual quantities or directions?

This list is not intended to be all inclusive. A 'yes' answer to any of the questions listed does not necessarily equate to a refusal to fill. A 'yes' answer means that the pharmacist has a responsibility to follow up with either the patient and/or prescriber for additional information to satisfy the good faith requirements. Pharmacists shall use their professional judgment when determining if the elements of good faith are present prior to dispensing controlled substance prescriptions.

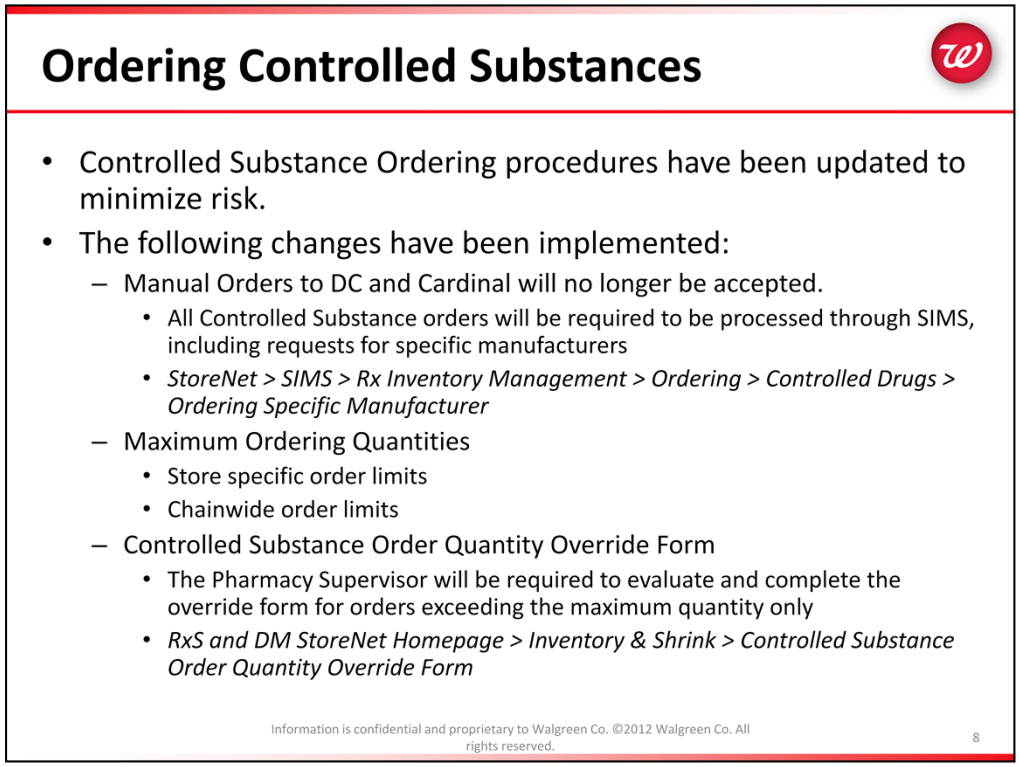
It is important that leadership supports our pharmacists who make appropriate good faith dispensing decisions.




Now that we understand the validation steps for GFD, here is how everyone plays a role in the process.

Everyone in the pharmacy has a role in ensuring that the elements of Good Faith Dispensing are met. While all pharmacists and technicians have an obligation to assist with validation of Good Faith Dispensing requirements during the dispensing process, the **Product Review/RFP (Retail Fill Process) Pharmacist** has the ***ultimate responsibility*** for ensuring that the elements of Good Faith are present.

During the Product Review/RFP process, the pharmacist is attesting not only that the product is correct but also that Good Faith Dispensing guidelines have been validated and documented appropriately. The goal is that all elements of Good Faith Dispensing have been validated **before** getting to the Product Review/RFP Pharmacist. The Product Review/RFP Pharmacist should then be able to confirm the elements of Good Faith Dispensing have been met and continue with the dispensing process.




**Talking Points:**

Following up on prior email communication, ordering of controlled substances has been restricted to minimize and monitor risk.

Manual Orders to DC and Cardinal for all Controlled Substances will no longer be accepted, this includes phone, email and online orders placed through Cardinal. Orders for specific manufacturers will also be required to be processed through SIMS. Follow the pathway shown here.

Stores will have a maximum quantity per order (regardless of frequency) for specific controlled substances.

There are two limits in place:

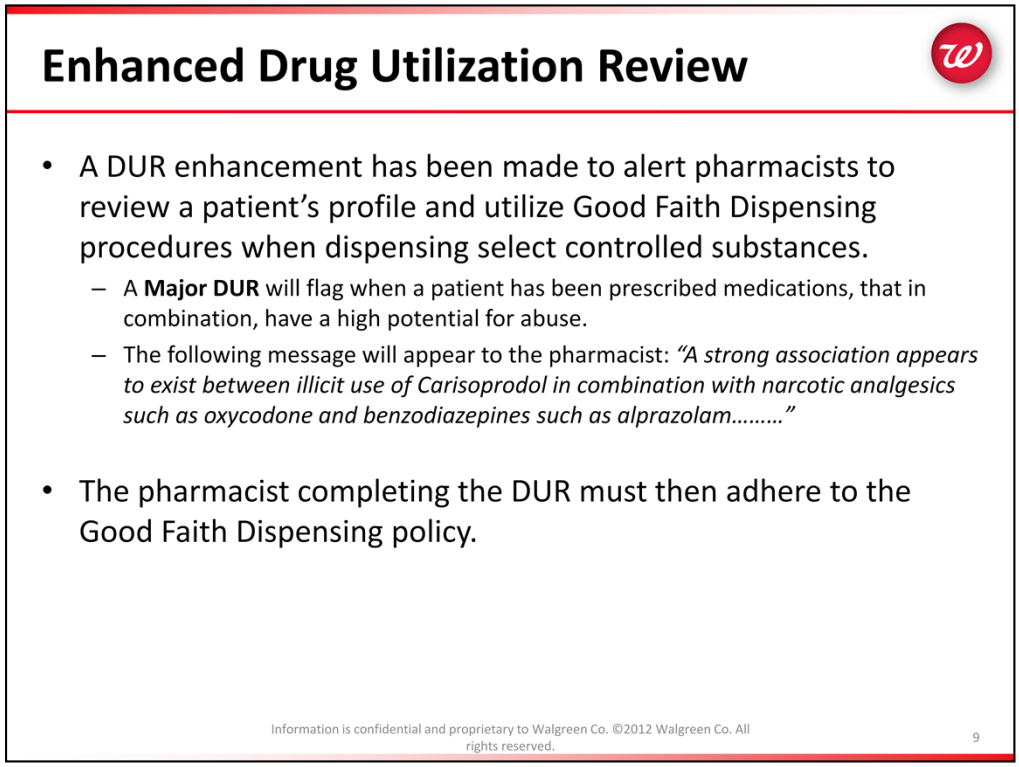
1) Store Specific Order Limits: SIMS will limit orders based on a product's sales history and any negative/positive adjustments to inventory on-hands.

2) Chainwide Order Limits: Specific controlled substances will be limited to by rx order to a predetermined quantity that will be the same at all stores.

Currently, this affects the following medications: Alprazolam 2mg, Carisoprodol 350mg, Hydromorphone 2mg & 4mg, Oxycodone 15mg & 30mg, Methadone 5mg & 10mg. These limitations effect approximately 80 stores for each order limit.

If the quantity ordered exceeds the maximum, the order will default to the maximum allowed.

Orders placed by stores that exceed the maximum qty allowed, either for that particular store or based on corporately determined line limits, will be blocked. District Leadership are required to evaluate if the order is legitimate. If approved by leadership, the Pharmacy Supervisor (or DM if RXS is not available) is able to place the order by submitting the Controlled Substance Order Quantity Override Form (located on *StoreNet >RxS and DM StoreNet Homepage > Inventory & Shrink > Controlled Substance Order Quantity Override Form).*



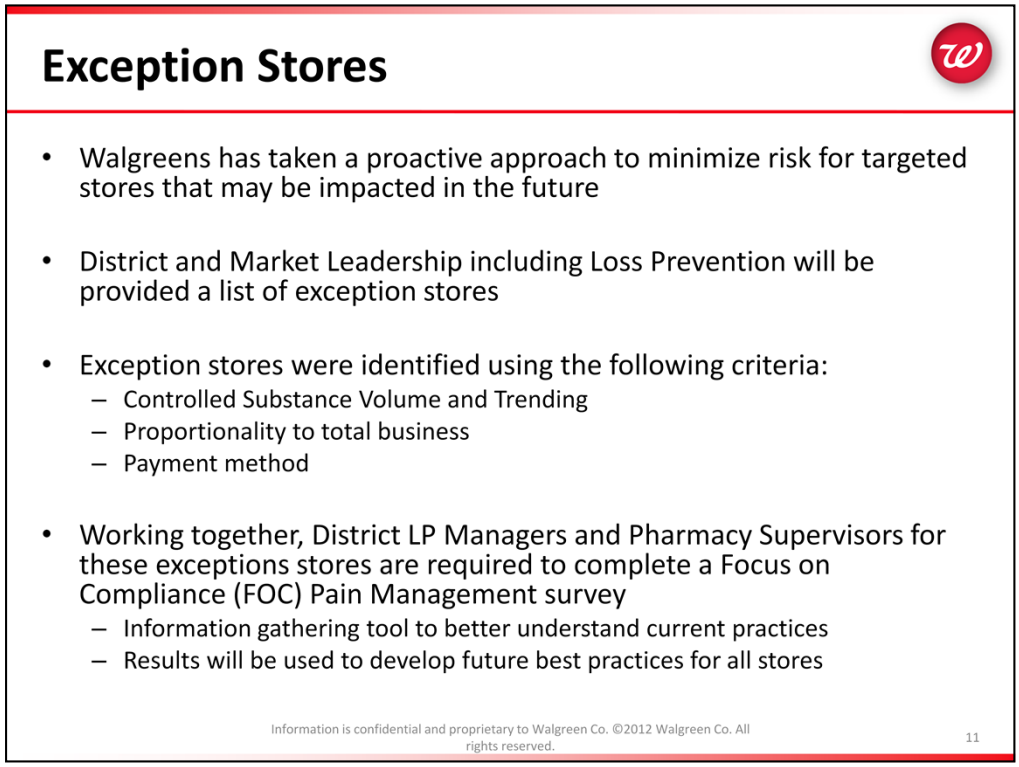

Select controlled substances (e.g. Soma, Xanax and Oxycodone), when combined, have been identified as potential medications of abuse.

To assist the pharmacist in evaluating prescriptions of potential abuse, a MAJOR Drug Utilization Review (DUR) will appear for patients who have been prescribed a combination of the following: 1) Soma (Carisoprodol) and Oxycodone or 2) Soma (Carisoprodol) and Xanax (Alprazolam).

This notification will indicate to the pharmacist to use the Good Faith Dispensing policy to evaluate the prescription prior to dispensing to the patient.

At this moment, the DUR notification applies to the medications listed above, however, as potential abusive combinations are identified , we will address accordingly.

- Overview
- Review updated policies & procedures
- Exception store visits
- Future Enhancements
- Call to action and next steps




[Divisional Loss Prevention Director]

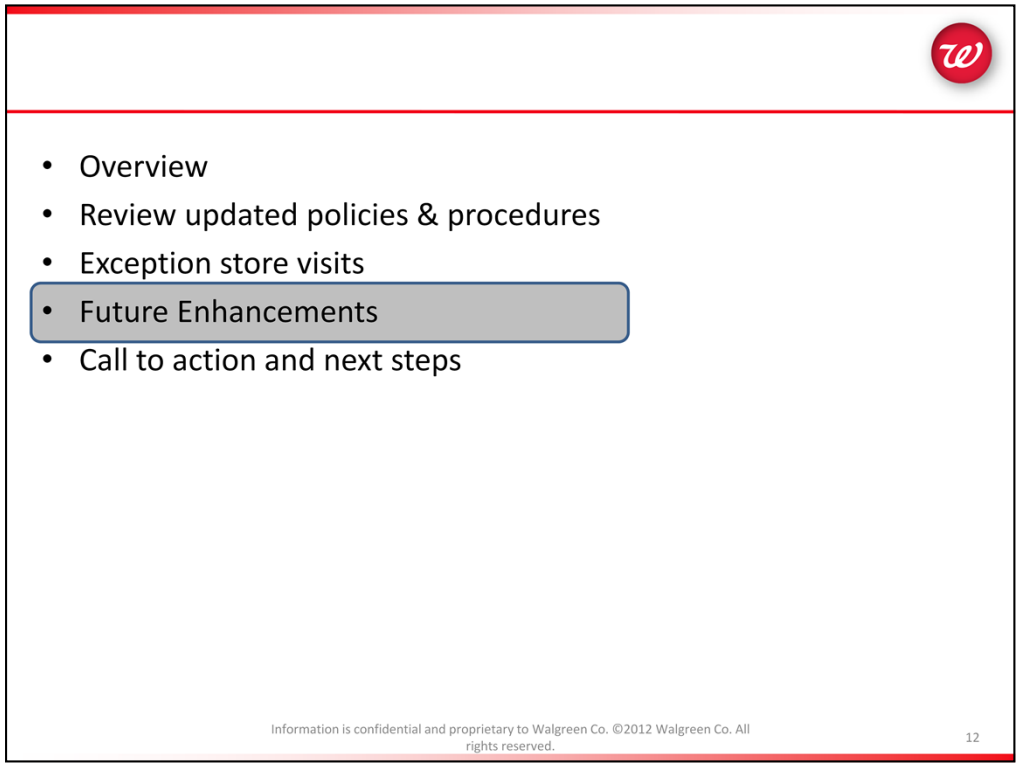
In addition to the enhancements made to how our pharmacy staff members currently process and dispense controlled substance, a proactive approach has been developed to minimize the risk for targeted stores that may be impacted in the future.

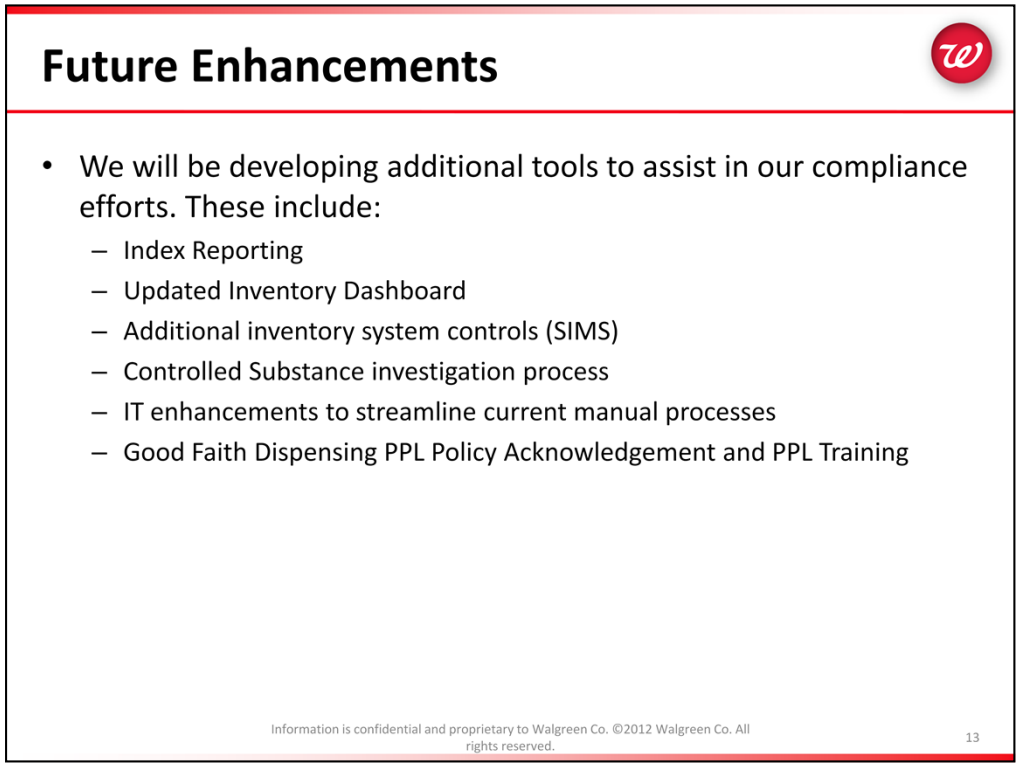
After this webinar, select District and Market leadership will be provided a list of exception stores that have been identified as high risk stores.

To determine which stores would be included on this list, all of the stores in the company were ranked based on their dispensing history of controlled substances, using the criteria noted on the slide. The top stores were then identified as exception locations.

Both the District Loss Prevention Manager and the Pharmacy Supervisor, working together as a team, are required to visit each exception store and conduct a Focus on Compliance survey. After each store visit is complete, the DLPMs will be tasked with actually entering the information gathered in the store into the on-line survey.

This task is not an audit. The information gathered from these exception stores will help to develop best practices that will help all of our pharmacies in the Walgreens Family of Companies.


• Overview
• Review updated policies & procedures
• Exception store visits
• Future Enhancements
• Call to action and next steps
Information is confidential and proprietary to Walgreen Co. ©2012 Walgreen Co. All rights reserved.
12

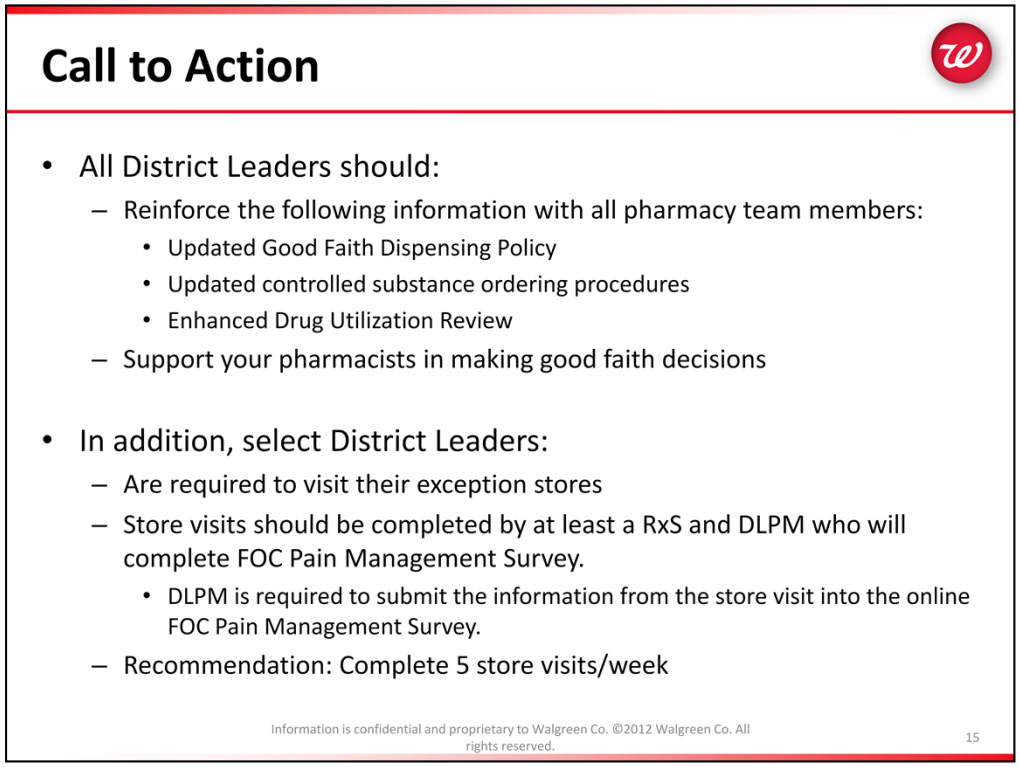



We will continue to enhance our current processes and implement new procedures to assist with our compliance efforts and to minimize future risk for DEA action.

These enhancements include corporate, market and district reporting tools, inventory controls, Controlled Substance Investigation (Escalation) process, future IT enhancements and additional training tools.

All Pharmacists and Technicians will be assigned the GFD Policy PPL later this month to read and acknowledge the updated policy.

- Overview
- Review updated policies & procedures
- Exception store visits
- Future Enhancements
- Call to action and next steps




What are your responsibilities? District leadership is required to communicate this information to your stores. We will provide an abbreviated version of this presentation to assist in communicating the Controlled Substance Action Plan with your stores.

It is imperative that ALL pharmacy team members understand the updated policies and procedures when handling controlled substances.

Again, we must ensure that our pharmacists are comfortable with following the Good Faith Dispensing policy and making appropriate decisions. Leadership is responsible for supporting our pharmacists with these decisions.

In addition, stores will receive a compass communication notifying them of the updated Good Faith Dispensing Policy.

Select district leaders will receive a list of exception stores later today and will be required to complete their store visits over the next few weeks.

# Questions

# Controlled Substance Action Plan

June 11, 2012

# Agenda

- Overview
- Review updated policies & procedures
- Future Enhancements
- Call to action and next steps

# Overview

- Due to recent action taken by the DEA, select policies and procedures have been updated to ensure our pharmacists and stores are compliant when dispensing controlled substances.

- Corresponding enhancements include:
  - Update to the Good Faith Dispensing Guidelines
  - Revised Ordering Procedures for Controlled Substances
  - Drug Utilization Review Enhancements

- Overview
- Review updated policies & procedures
- Future Enhancements
- Call to action and next steps

# Good Faith Dispensing Policy

- The Good Faith Dispensing Policy has been updated to provide Pharmacists additional resources for making decisions when dispensing controlled substance prescriptions.

- The following components have been updated:
  - Prescription Validation Procedures
  - Roles and Responsibilities of each pharmacy team member

- Pathway to Good Faith Dispensing Policy
  - *Storenet > RxOps > Pharmacy Policies and Procedures > Filling Prescriptions > Controlled Substance Prescriptions and Good Faith Dispensing*

# Validation Procedures for Good Faith Dispensing (GFD)

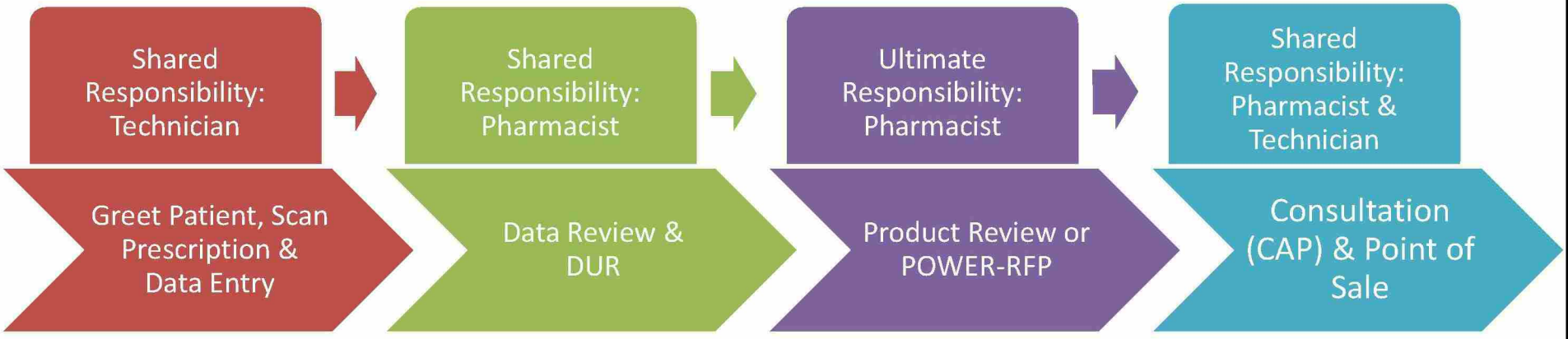
## Validation Tools

1. **Patient ID**
   - Verify and Document ID if the patient doesn't have a relationship with the pharmacy
   - Follow state specific guidelines
2. **Prescriber**
   - Verify Prescriber DEA number
   - Use DEA website if necessary
3. **PDMP**
   - Utilize to obtain additional information to help determine validity of prescription
   - State specific
4. **Data/DUR Review**
   - Review patient profile to resolve and document any associated DURs
5. **Evaluate GFD guidelines**
   - Ensure usual course of professional practice
   - Verify noticeable trends with prescribers or patients
   - Verify prescriptions have not been altered or forged

## Actions after Validation

6. **Document**
   - Document all efforts used to validate good faith dispensing
7. **RPh Action**
   - Determine how to proceed after using GFD guidelines:
     - Dispense
     - Not valid to dispense
     - Refuse to dispense
8. **Notify DEA**
   - Notify local DEA office of refusal to fill if prescription is forged, altered or issued outside of usual course of professional practice

# Everyone Plays a Role in the GFD Process




- Technician to verify and scan patient ID (GFD)
- Technician to alert RPh of questionable rxs
- Determine if Prescriber has a valid DEA

- Validate Prescriber Scope of Practice
- Review PDMP (state specific) – non-POWER only
- Verify script with PBR
- Evaluate elements of GFD
- Review Patient Profile and resolve DURs
- Document information
- Action: Determine if appropriate to fill

- Confirm GFD validation and documentation was completed, including PDMP in POWER
- If not, then complete GFD guidelines to determine if prescription should be dispensed.
- Final Responsibility to complete GFD
- Action: Determine if appropriate to fill

- Check/ Verify ID
- Follow up on any open issues related to GFD guidelines.
- Consult patient

# Ordering Controlled Substances

- Controlled Substance Ordering procedures have been updated to minimize risk.
- The following changes have been implemented:
  - Manual Orders to DC and Cardinal will no longer be accepted.
    - All Controlled Substance orders will be required to be processed through SIMS, including requests for specific manufacturers
    - *StoreNet > SIMS > Rx Inventory Management > Ordering > Controlled Drugs > Ordering Specific Manufacturer*
  - Maximum Ordering Quantities
    - Store specific order limits
    - Chainwide order limits
  - Orders exceeding the maximum quantities
    - Pharmacy Managers must contact their Pharmacy Supervisor for approval
    - If approved, the Pharmacy Supervisor will approve and submit the order

# Enhanced Drug Utilization Review

- A DUR enhancement has been made to alert pharmacists to review a patient's profile and utilize Good Faith Dispensing procedures when dispensing select controlled substances.
  - A **Major DUR** will flag when a patient has been prescribed medications, that in combination, have a high potential for abuse.
  - The following message will appear to the pharmacist: *"A strong association appears to exist between illicit use of Carisoprodol in combination with narcotic analgesics such as oxycodone and benzodiazepines such as alprazolam……"*

- The pharmacist completing the DUR must then adhere to the Good Faith Dispensing policy.

- Overview
- Review updated policies & procedures
- Future Enhancements
- Call to action and next steps

# Future Enhancements

- We will be developing additional tools to assist in our compliance efforts. These include:
  - Index Reporting
  - Updated Inventory Dashboard
  - Additional inventory system controls (SIMS)
  - Controlled Substance investigation process
  - IT enhancements to streamline current manual processes
  - Good Faith Dispensing PPL Policy Acknowledgement and PPL Training

- Overview
- Review updated policies & procedures
- Future Enhancements
- Call to action and next steps

# Call to Action

- Store leadership are to:
  - Reinforce the following information with all pharmacy team members:
    - Updated Good Faith Dispensing Policy
    - Updated controlled substance ordering procedures
    - Enhanced Drug Utilization Review
  - Support your pharmacists in making good faith decisions

# Questions